ARTHROSAMID®

SAFE AND SUSTAINED PAIN RELIEF WITH A SINGLE INJECTION[1]

A non-degrading viscoelastic hydrogel for adults with knee osteoarthritis

contura
ORTHOPAEDICS

Osteoarthritis in the knee

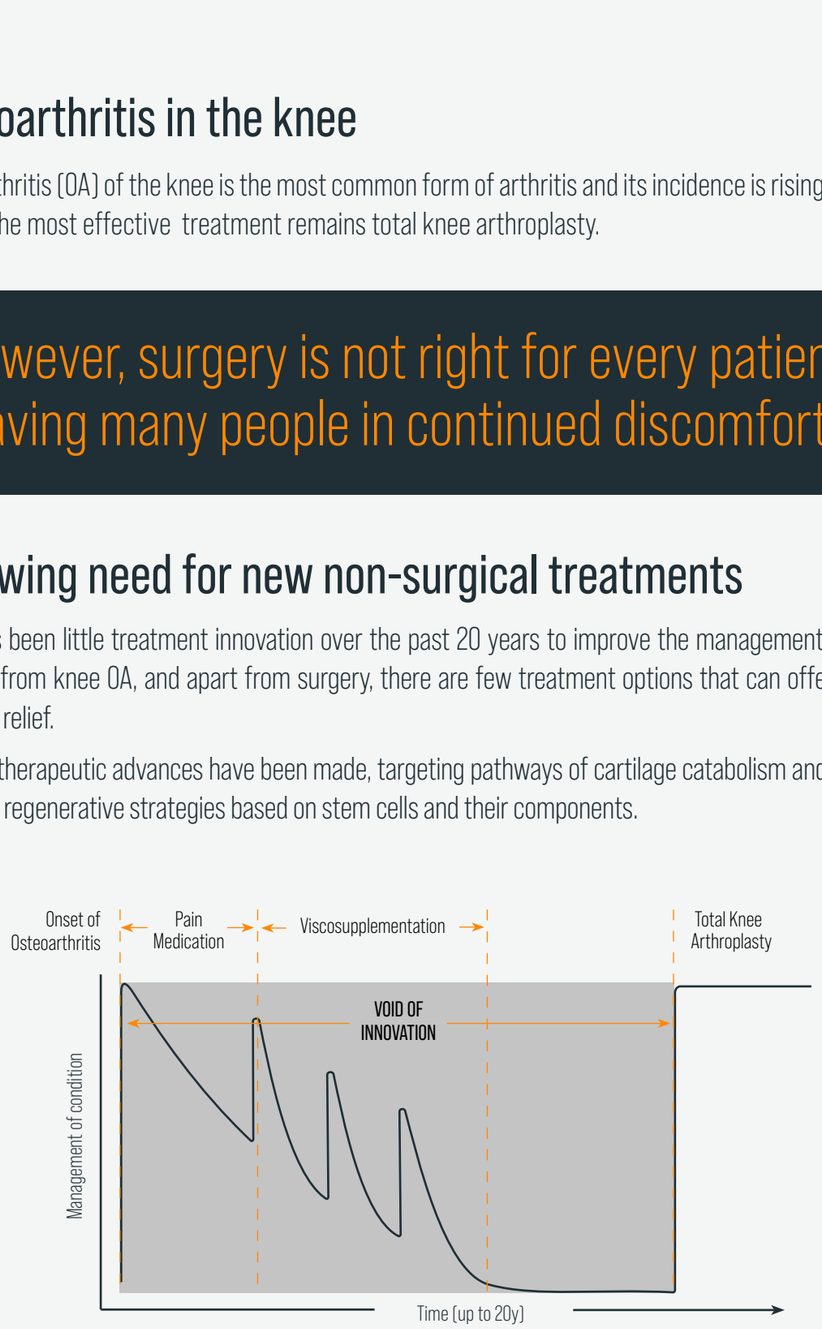
Osteoarthritis (OA) of the knee is the most common form of arthritis and its incidence is rising. Without a cure, the most effective treatment remains total knee arthroplasty.

> However, surgery is not right for every patient, leaving many people in continued discomfort.

A growing need for new non-surgical treatments

There has been little treatment innovation over the past 20 years to improve the management of patients suffering from knee OA, and apart from surgery, there are few treatment options that can offer long-term symptom relief.

Potential therapeutic advances have been made, targeting pathways of cartilage catabolism and anabolism, as well as regenerative strategies based on stem cells and their components.



> Despite the new therapies and non-pharmacological interventions, many patients still require premature surgery or remain in pain, significantly affecting their quality of life.

However this is about to change...

iPAAG

Introducing Intra-articular Polyacrylamide Hydrogel (iPAAG)

a novel therapeutic concept

Arthrosamid® is an intra-articular polyacrylamide hydrogel injection (iPAAG). It is a non-biodegradable single-dose injection that delivers long-acting pain relief, improving the quality of life for patients with knee osteoarthritis.[1]

What is iPAAG?

Intra-articular polyacrylamide hydrogel (iPAAG) is made of 2.5% cross-linked polyacrylamide and 97.5% water.

Biocompatible
Permeable to salts and organic molecules the hydrogel is able to integrate with soft tissue.

Viscoelastic
Cross-linked chains of polymer allow flexible shear.

Non-degradable
Structural stability of hydrogel provides longevity of action.

Arthrosamid® increases viscosity within the synovial fluid, providing lubrication that acts as a cushion to deliver long-acting and sustained pain relief in a single injection.[1]

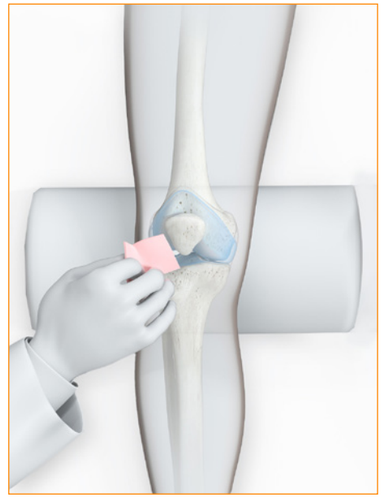
Arthrosamid® is **safe** for intended use[2]

More than **700,000** hydrogel units have been used for various indications in the body

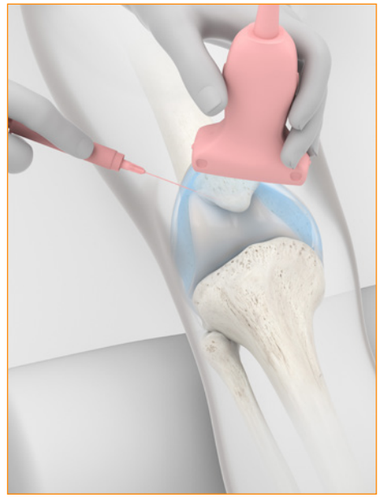
Undergone over **two decades** of research and development[3]

A familiar technique

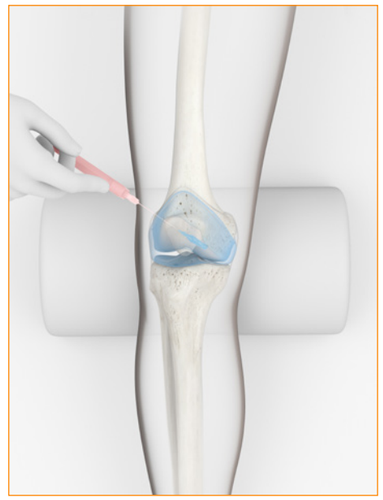
Arthrosamid® treatment is a minimally invasive outpatient procedure.[4] It should be performed under local anaesthesia, with ultrasound guidance.



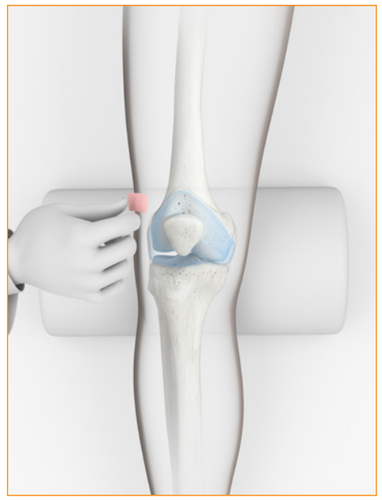
Step 1 It is essential that at least 5 cm around the injection site is swabbed prior to the injection. Local anaesthetic is used to numb the injection site. The same needle is set in place for the whole procedure.[3]



Step 2 Remove joint effusion, if present, before injecting Arthrosamid®. Injection should be performed with the help of ultrasound in the lateral, proximal recess.[3]



Step 3 Remove the protective Tip Cap from the Arthrosamid® syringe and inject hydrogel. This is repeated until 6 ml of Arthrosamid® is delivered.[3]



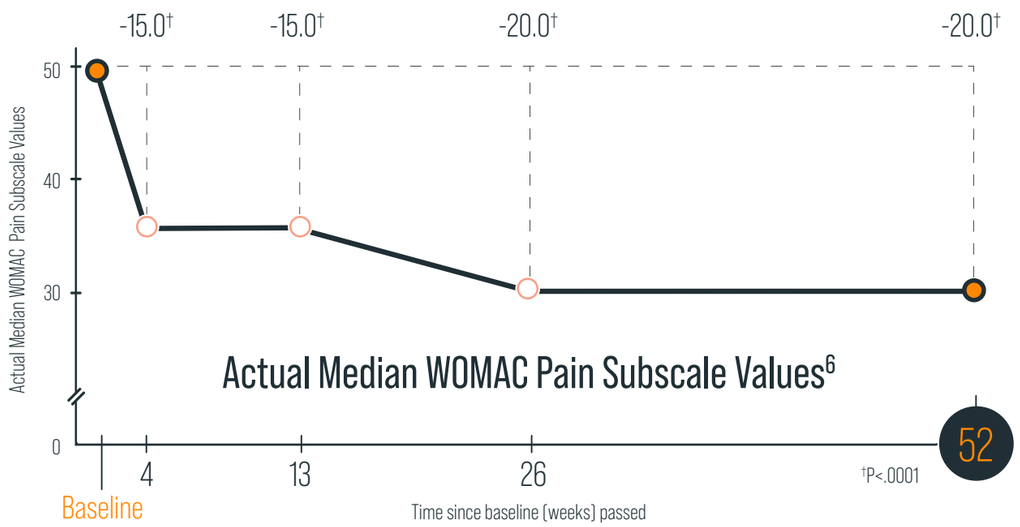
Step 4 Remove the needle and place a plaster over the injection site.

Polyacrylamide Hydrogel Injection for Knee Osteoarthritis

52 Week Prospective Study. 'IDA study'[1,5]

N=49	3:2 female, male. Mean age 70 with symptomatic and radiographically confirmed knee OA.
Primary outcome	Change in WOMAC* pain subscale.
Secondary outcome	WOMAC stiffness and function subscales, Patient Global Assessment of disease impact (PGA) and proportion of OMERACT-OARSI responders.
Follow up	4, 13, 26 and 52 weeks.
Injection volume	6 ml.

>70% of patients had a response larger than MCID** for all 3 WOMAC subscales at week 26.[1,5] Pain and physical function were maintained at 52 weeks.[6]



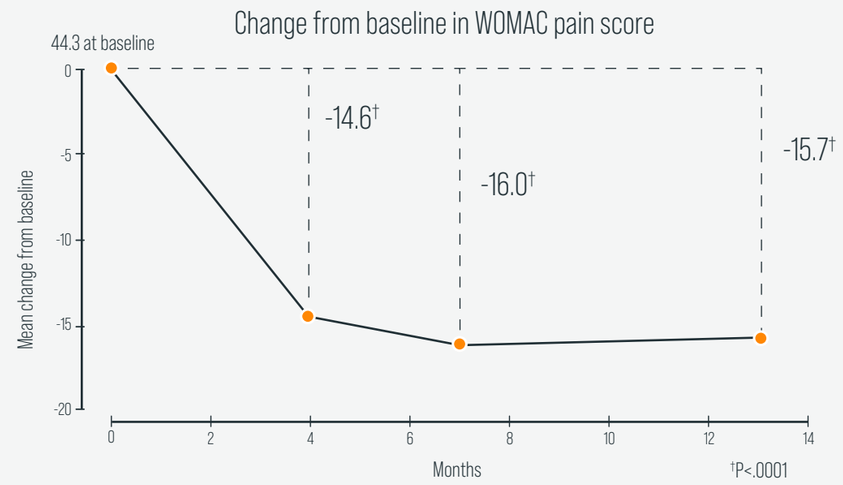
Similar results were found for OMERACT-OARSI and PGA scale[1,5]

*WOMAC or The Western Ontario and McMaster Universities Osteoarthritis Index is a measure of symptoms and physical disability
**MCID - Minimal Clinically Important Difference

Intra-Articular 2.5% Polyacrylamide Hydrogel for the Treatment of Knee Osteoarthritis

An Observational Proof-of-Concept Study[7]

Efficacy



Safety

Safety of Intra-Articular Polyacrylamide Hydrogel for the Treatment of Knee Osteoarthritis Symptoms

56 Week Retrospective Case Series.'DAISY study'[2]

Table 1: Number (proportions) of patients reporting adverse events/discomfort in relation to treatment with Arthrosamid®. No serious adverse incidents occurred due to Arthrosamid® treatment.

Patients describing no adverse events or discomfort	Reported adverse events or discomfort
N= 66 (73%)	N = 25 (27%)

Table 2: Patient reported events
All patients reporting pain described the duration of the event to be resolved within weeks.

Adverse event registered	No.	Proportion
Sensation of distension	15	36.6%
Pain from target knee	7	17.1%
Reduced range of motion	4	9.8%
Other	15	36.4%
Total	41	100%

No patients had severe adverse events linked to Arthrosamid®[1,5]

For a full list of adverse events contact us at: https://www.arthrosamid.com

ARTHROSAMID®

SAFE AND SUSTAINED PAIN RELIEF WITH A SINGLE INJECTION[1]

Ordering information

Contura Orthopaedics Limited
14 Took's Court, London EC4A 1LB
United Kingdom
orders@arthrosamid.com

Further information is available at Arthrosamid.com or contact us to use Arthrosamid® in your osteoarthritis knee patients at enquiries@arthrosamid.com

INDICATIONS, PATIENT GROUP AND USAGE

Arthrosamid® is intended to be used for symptomatic treatment of adult patients with knee osteoarthritis.

CONTRAINDICATIONS[3]

Arthrosamid® should not be injected:

- If an active skin disease or infection is present at or near the injection site
- If the joint is infected or severely inflamed
- If the patient has previously received treatment with a different non-absorbable injectable/implant
- If the patient has received a knee alloplasty or has any foreign material in the knee
- If the patient has undergone knee arthroscopy within the last 6 months
- In haemophilia patients or in patients in uncontrolled anti-coagulant treatment

If a degradable intra-articular injectable such as hyaluronic acid is present, it must be expected to be absorbed according to manufacturer's information for the specific product before injection with Arthrosamid®.
A different non-absorbable implant should not subsequently be injected.
For more information, read the IFU for full details about Warnings and Precautions.
The IFU is also available from http://www.arthrosamid.com or info@arthrosamid.com.

1. Bliddal H, Overgaard A, Hartkopp A, Beier J, Conaghan PG, et al. (2021) Polyacrylamide Hydrogel Injection for Knee Osteoarthritis: A 6 Months Prospective Study. J Orthop Res Ther 6: 1188.
2. Overgaard, A., Bliddal, H., Henriksen, M., 2019. Safety of Intra-Articular Polyacrylamide Hydrogel for the Treatment of Knee Osteoarthritis Symptoms: A Retrospective Case Series. Clin Ortho Adv Res J: COARJ-100001.
3. Arthrosamid, Information For Use. Release Date November 2020 10082-002.
4. Goldman, D.T., Piechowiak, R., Nissman, D., Bagla, S., Isaacson, A., 2018. Current Concepts and Future Directions of Minimally Invasive Treatment for Knee Pain. Current rheumatology reports 20, 54.
5. Bliddal H, Overgaard A, Hartkopp A, Beier J, Conaghan PG, et al., 2021. Polyacrylamide Hydrogel Injection for Knee Osteoarthritis: Results of a 52 Week Prospective Study. Poster presented at OARSI Connect 2021.
6. Data on file.
7. Henriksen M, Overgaard A, Hartkopp A, Bliddal H. Intra-articular 2.5% polyacrylamide hydrogel for the treatment of knee osteoarthritis: an observational proof-of-concept cohort study. Clin Exp Rheumatol. 2018.

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